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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,872	04/02/2002	Jean-Pierre Blareau	33339/242251	8072

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,872	BLAREAU ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5,7-10 and 12-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on August 1, 2006 has been received and entered into the case. Claims 6 and 11 are canceled; claims 12 – 15 are added; claims 1 – 5, 7 – 10 and 12 – 15 are pending.

Newly submitted claims 14 and 15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a method for increasing resistance to infection in a subject. The groups are independent and distinct, as evidenced by the fact that the method could be practiced with other materially different products such as colostrum, lactoferrin or Echinacea. Since applicant has received an action on the merits for the invention elected on December 16, 2005, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14 – 15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1 – 5, 7 – 10 and 12 – 13 have been considered on the merits.

It is noted that the Examiner for this application has changed. The new Examiner is Ruth A. Davis. Contact information is provided at the conclusion of this Office Action.

Specification

The objections to the disclosure are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, line 2, "the bringing into contact" lacks sufficient antecedent basis.

Claim 5 is rendered vague and indefinite for reciting "is used" because it is unclear what is being used, and for what purpose.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 – 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mutai et al. (US 4187321).

Applicant claims an immunostimulant milk product, that is obtained by a bioconversion of a milk substrate with Bifidobacteria under conditions unfavorable to fermentation by the bacteria, and sterilizing and/or desiccating the milk product formed. During conversion, there are about 10^7 – 10^9 CFU per ml milk substrate, and the final population is from 10^5 – 10^9 CFU per ml product; the pH of the substrate is about 6.3 – 7 and the final product pH of about 6 – 7; the substrate is in contact with the bacteria for about 6 – 7 hours; and the strain of Bifidobacterium is CNCM I-2219. Specifically, the milk product is a food product that is dehydrated.

Mutai teaches food milk products that are obtained by bioconversion of a milk substrate and Bifidobacteria (abstract), wherein the food product is freeze dried (desiccated or dehydrated) (examples).

Although Mutai does not teach the claimed method by which the product is made, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) In addition, while Mutai does not specifically identify the product

is immunostimulatory, the products appear to be the same. Thus, the composition of Mutai must also, inherently be immunostimulatory.

Therefore, the reference anticipates the claimed subject matter.

5. Claims 1 – 5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yajima et al. (US 5230912).

Applicant claims an immunostimulant milk product, that is obtained by a bioconversion of a milk substrate with Bifidobacteria under conditions unfavorable to fermentation by the bacteria, and sterilizing and/or desiccating the milk product formed. During conversion, there are about 10^7 – 10^9 CFU per ml milk substrate, and the final population is from 10^5 – 10^9 CFU per ml product; the pH of the substrate is about 6.3 – 7 and the final product pH of about 6 – 7; the substrate is in contact with the bacteria for about 6 – 7 hours; and the strain of Bifidobacterium is CNCM I-2219. Specifically, the milk product is a food product that is sterilized.

Yajima teaches a milk food produced by culturing milk substrate with Bifidobacteria (abstract), wherein the food product is later sterilized (col.4 line 49-59)

Although Yajima does not teach the claimed method by which the product is made, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly

different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) In addition, while Yajima does not specifically identify the product is immunostimulatory, the products appear to be the same. Thus, the composition of Yajima must also, inherently be immunostimulatory.

Therefore, the reference anticipates the claimed subject matter.

6. Claims 1 – 5, 7 – 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mutai et al. (US 4091117).

Applicant claims an immunostimulant milk product, that is obtained by a bioconversion of a milk substrate with Bifidobacteria under conditions unfavorable to fermentation by the bacteria, and sterilizing and/or desiccating the milk product formed. During conversion, there are about 10^7 – 10^9 CFU per ml milk substrate, and the final population is from 10^5 – 10^9 CFU per ml product; the pH of the substrate is about 6.3 – 7 and the final product pH of about 6 – 7; the substrate is in contact with the bacteria for about 6 – 7 hours; and the strain of Bifidobacterium is CNCM I-2219. Specifically, the milk product has a pH or 6 – 7; is a food product that has a pH of 6 – 7.5; 6.5 – 6.9; or is dehydrated.

Mutai teaches food milk products that are obtained by bioconversion of a milk substrate and Bifidobacteria (abstract), wherein the milk product has a pH of 4 – 7, and can be powdered (or desiccated) (col.5 line 10-45). Mutai teaches the number of bactiera are 10^7/ml (col.5 line 10-16).

Although Mutai does not teach the claimed method by which the product is made, these limitations are considered to be product by process type limitations. The patentability of a

product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) In addition, while Mutai does not specifically identify the product is immunostimulatory, the products appear to be the same. Thus, the composition of Mutai must also, inherently be immunostimulatory.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mutai et al. (US 4091117) in view of Wang et al. (US 6034130) and/or Lucas et al. (US 4756926).

Applicant claims an immunostimulant milk product, that is obtained by a bioconversion of a milk substrate with Bifidobacteria under conditions unfavorable to fermentation by the bacteria, and sterilizing and/or desiccating the milk product formed. Specifically, the milk product is a food product that is sterilized.

Mutai teaches food milk products that are obtained by bioconversion of a milk substrate and Bifidobacteria (abstract), wherein the milk product has a pH of 4 – 7, and can be powdered (or desiccated) (col.5 line 10-45). Mutai teaches the food products include baby food (col.5 line 35-40).

Although Mutai does not teach the claimed method by which the product is made, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) In addition, while Mutai does not specifically identify the product

is immunostimulatory, the products appear to be the same. Thus, the composition of Mutai must also, inherently be immunostimulatory.

Mutai does not teach the food product is sterilized. However, the reference does teach that the food products may be baby food. At the time of the claimed invention, it was well known and established in the art that baby food is sterilized. In support, Wang teaches sterilizing baby food (col.4 line 20-26), and Lucas teaches infant foods that are sterilized (col.8 line 40-45). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to sterilize the baby food disclosed by Mutai, since it was routinely practiced as evidenced by the cited references.

Response to Arguments

Applicant argues that the references do not teach each of the claimed elements in that they do not teach the process by which the product is made or the fact that the composition is immunostimulant. Applicant additionally argues that the references do not teach the processes of sterilization or desiccation. Applicant states that the references do not require a food product with out viable Bifidobacteria, but contain viable Bifidobacteria.

However, these arguments fail to persuade because as stated in the rejections above, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process.

Regarding the immunostimulatory properties of the composition, the compositions appear to be the same, as they are made by the same, if not similar methods; they have the same pH and number of CFUs. Thus, the compositions of the cited references must also be immunostimulatory. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

Regarding applicant's assertion that the references do not teach sterilization or desiccation, the rejections above indicate that such steps are, in fact, disclosed by the cited references.

Finally, regarding applicant's assertion that the claimed composition contains non-viable bacteria, it is noted that the claims do not require a food product without viable bacteria. Thus, this argument is not commensurate in scope with the claims. It is noted that the claims are directed to a composition that contains bacteria in the same amounts as those disclosed by the cited references.

For these reasons and those stated in the rejections above, the claims are rejected.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

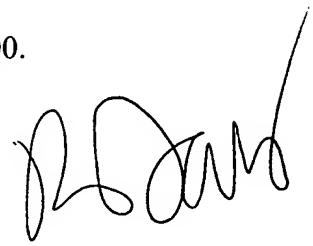
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



November 6, 2006